Commonwealth of Virginia Department of General Services Division of Consolidated Laboratory Services Richmond, Virginia

Tuning Fork Laboratory Quality Manual Checklist

Quality Manual Completeness Checklist for Laboratories Performing Certification of Tuning Forks

Facility Name: Lab ID: TFC –

Protocol for the Certification of Laboratories Performing Certification of Tuning Forks, Rev. 5

<u>LABORATORY USE</u>: RECORD THE QUALITY MANUAL OR SOP <u>PAGE NUMBER</u> & <u>SECTION NUMBER</u> UNDER THE "LABORATORY REFERENCE" COLUMN INDICATING WHERE EACH REQUIREMENT CAN BE FOUND. RETURN THIS COMPLETED FORM TO DCLS PRIOR TO THE ON-SITE EVALUATION ALONG WITH CURRENT COPIES OF THE QUALITY MANUAL AND ASSOCIATED DOCUMENTS.

Protocol for the Certification of Laboratories Performing Certification of Tuning Forks, Section V.B. At a minimum, the following information must be included or referenced in the Quality Manual:

Quality Manual Requirement	Laboratory Reference	DCLS INTERNAL USE ONLY		
		Document Compliant?	Reviewer's Notes	
§ V.B.1 Company name and address				
§ V.B.2 Statements affirming the laboratory's commitments to quality assurance and data integrity				
§ V.B.3 Minimum personnel qualifications including education and any specialized training in communications electronics, radar calibration and repair, or frequency measurement				
§ V.B.4 Log of printed names, handwritten initials and signatures of all laboratory personnel authorized to perform tuning fork testing, data review, and/or certificate notarization				
§ V.B.5 List of all testing equipment—including manufacturer, model, and serial number—used in the certification procedure				
§ V.B.6 Information describing the accuracy, range and reproducibility for each instrument and item of support equipment used for the testing and certification of tuning forks (An excerpt from the instrument manual with this information will satisfy the requirement)				
§ V.B.7 Corrective Action Policy for response when instrumentation fails to meet fitness for use acceptance criteria				
§ V.B.8 Schedules for instrument calibration and maintenance including requirements for documenting calibration and maintenance				

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§ V.B.9 Description of circumstances that would require recertification of reference tuning forks (e.g., trauma, damage or change in performance)						
§ V.B.10 Description of processes and procedures for ensuring traceability of measurements to nationally recognized standards (may include calibration tone source by name, address, and telephone number or other means of documenting traceability, for example daily evaluation of equipment against a standard signal from WWV)						
Description of Procedures being performed, equipment being used, calculations, and examples, adjustments (if any), and references. This information may be included in the Quality Manual or may be a separate Standard Operating Procedure (SOP). At a minimum, the information shall include:						
§ V.B.11.a Sample receiving and tracking procedures						
§ V.B.11.b Sample Rejection Policy describing the circumstances under which a tuning fork would not be accepted for testing						
§ V.B.11.c Procedures for labeling and disposition of rejected tuning forks						
§ V.B.11.d Instructions for instrument setup, fitness for use testing and documentation, and acceptance criteria (to include striking the tuning fork on a nonmetallic object and waiting for a stable output - approximately 3 seconds - before recording the observed frequency)						
The procedure and criteria for testing tuning forks submitted by law enforcement agencies for certification and documenting test results, to include:						
§ V.B.11.e.i Reference tuning forks tested prior to beginning testing and at the conclusion of each day on which testing occurred						
§ V.B.11.e.ii Frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification						
§ V.B.11.e.iii Temperature of the test environment recorded prior to testing each sample set and at the end of the sample set						
§ V.B.11.e.iv Temperature of the test environment not less than 20°C (68°) and not greater than 30°C (86° (NOTE: A laboratory should consider monitoring humidity at the testing site if the possibility of exceeding 10%-85% is suspected.)						
§ V.B.11.e.v At least 2 frequency observations recorded and averaged for the calculation of MPH						
§ V.B.11.e.vi A description of calculations used (with sufficient detail to ensure the report produced by the analyst can be verified by reconstructing the calculation)						

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<u>Calculations</u> K band: Speed, mph = Average observed Ka band: Speed, mph = Average observed			minal microwave frequency, GHz)		
§ V.B.11.e.vii Each page of test documentation dated and initialed by the analyst					
Process for reviewing and reporting of test data and o	alculations,	to include:			
§ V.B.11.f Process for reviewing and reporting test data and calculations					
§ V.B.11.f.i Data review documented with date and initials of reviewer					
§ V.B.11.f.ii Final reports notarized					
§ V.B.11.g Processes for customer notification as well as labeling and disposition of tuning forks that fail the certification testing					
Procedure for Technician Training: Description of the documentation, <u>to include</u> :	complete tr	raining proces	ss and supporting		
§ V.B.12.a Concise statement of training goals and expected results					
§ V.B.12.b Learning objectives and expectations upon completion of training (clear statement of the capabilities expected of the technician upon completion of training)					
§ V.B.12.c Learning methods and/or activities (specific actions facilitating the achievement of the learning objectives)					
§ V.B.12.d Documentation of training (evidence, with signatures and dates, that the learning activities were performed and evaluated)					
§ V.B.12.e Training effectiveness criteria (specific measures and criteria indicating the effectiveness of the training)					
§ V.B.12.f Evaluation of training (assessment of documentation against criteria to determine whether learning objectives were achieved)					
Demonstration of Capability—a procedure for establishing technician competence in testing and establishes acceptance criteria for the evaluation of analyst capability:					
§ V.B.13.a.i Each technician shall perform a minimum of 20 consecutive frequency observations of each reference tuning fork					
§ V.B.13.a.ii Each technician shall calculate the mean and standard deviation of each data set					
§ V.B.13.b The mean frequency of oscillation of each reference tuning fork shall be within ±0.5% of that specified by the manufacturer or the most recent independent certification					

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Record Retention Policy						
§ V.B.14.a.i Maintenance logs retained a minimum of three (3) years						
§ V.B.14.a.ii Calibration records retained a minimum of three (3) years						
§ V.B.14.a.iii Sample observation records retained a minimum of three (3) years						
§ V.B.14.a.iv Training records and Demonstrations of Capability retained a minimum of three (3) years						
Documentation practices						
§ V.B.14.b.i All handwritten data shall be recorded in ink						
§ V.B.14.b.ii Changes to laboratory records shall be made with a single strike-out line leaving the original entry visible						
§ V.B.14.b.iii Changes shall be documented with date and initials of person making the correction						
§ V.B.14.c Describe procedures for ensuring the security of electronic records						
The manual contains a sample copy of a certificate is	sued to cus	tomers <u>sho</u> v	ving the following:			
§ V.B.15.a Serial number or other unique identifier of the tuning fork						
§ V.B.15.b The frequency at which the tuning fork was found to oscillate and the corresponding MPH (miles per hour)						
§ V.B.15.c The designation of the radar frequency band within which the tuning fork is to be used						
§ V.B.15.d Date of certification testing						
§ V.B.15.e Signature of the analyst who performed the testing						
§ V.B.15.f Date, seal and signature of notarization						
§ V.B.15.g Any additional information required by court systems of the jurisdictions in which laboratory's clients are located						
The manual shall also contain:						
§ V.B.16 Change sheet to allow historic reconstruction of changes to the Quality Manual						
§ V.B.17 Annual review and signature sheet						
		DCLS Assessor Review Initials/Date:				

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CHECKLISTS ARE AN INTERVIEW/REVIEW TOOL USED BY ASSESSORS AND ARE NOT TO BE CONSIDERED AS A SUBSTITUTE FOR REQUIREMENTS OF THE PUBLISHED REFERENCE. CHECKLISTS ARE SUBJECT TO CHANGE. PLEASE NOTIFY DCLS IMMEDIATELY BY EMAIL OF ANY IDENTIFIED ERRORS OR OMISSIONS (LAB_CERT@DGS.VIRGINIA.GOV)

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